REMARKS

Claim Rejections under 35 U.S.C. § 102.

An invention is unpatentable under 35 U.S.C. § 102(b) ("Section 102(b)") if "the invention was patented . . . more than one year prior to the date of the application for patent in the United States. A Section 102(b) rejection is only appropriate, however, where the "reference fully discloses in every detail the subject matter of a claim." *Application of Foster*, 383 U.S. 966 (1966). For the reasons set forth below, Applicant submits that the reference cited by the Examiner does not teach each and every element of the claimed invention and thus does not anticipate the claimed invention.

I. The Moniz Reference

Applicant's claims 1 and 2 stand rejected under Section 102(b) as unpatentable over U.S. Pat. No. 5,288,491 to Moniz ("Moniz").

Moniz discloses a method for processing the noni plant into powder. Moniz also sets forth background information about the Morinda citrifolia plant and its uses. The Moniz reference to topical use of the leaves of the noni plant in the Caribbean for treatment of aches, pains, and tendinitis in no way anticipates the present invention. The present application is directed to providing an oral dose of Morinda citrifolia for consumption and makes no mention of topical application.

Further, Moniz fails to anticipate the step of "limiting undesired COX-1 inhibition relative to COX-2 inhibition by limiting the concentration of said dose" claimed by the present application. Applicant's claims are not directed to the general treatment of pain by the action of selective COX-2 inhibition. Rather, the present invention is directed to a particular dosage of Morinda citrifolia

designed to limit COX-1 inhibition relative to COX-2 inhibition. Such dosage is not inherent in the Morinda citrifolia plant itself since dosage of any plant is only inherently limited by the size of the plant. Rather, such dosage is in fact novel and non-obvious in that such limited dosage is contrary to traditional notions equating increased dosage with increased desired medicinal effects.

Applicant's claim 2 places further limitations on otherwise allowable subject matter and should not therefore be considered anticipated.

In light of the foregoing, Applicant respectfully submits that Moniz does not anticipate the claims of the present invention as each and every limitation of the claims of the present invention are not found therein. A withdrawal of this rejection is therefore respectfully requested.

Claim Rejections under 35 U.S.C. § 103.

An invention is unpatentable under 35 U.S.C. § 103(a) ("Section 103") "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

To establish a *prima facie* case of obviousness, three criteria must be met. "First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *In re John R. Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Any such suggestion must be "found in the prior

art, and not based on applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Indeed, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." MPEP § 2142.

A "clear and particular" showing of the suggestion to combine is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant's claims are not obvious in view of the prior art references.

I. Moniz, Nair, and Wadsworth References

Applicant's claims 1-14 stand rejected under Section 103 as unpatentable over Moniz in view of WIPO Publication No. WO 01/15553 ("Nair") and U.S. Pat. No. 6,254,913 ("Wadsworth"). Applicant respectfully submits that the above-referenced art, considered cumulatively, does not render the present invention obvious.

Indeed, the Examiner has disregarded significant claim elements in the present invention. For example, Applicant claims a limited dosage of Morinda citrifolia which operates to limit undesired COX-1 inhibition relative to COX-2 inhibition. Applicant finds no mention of this element in any cited reference, nor any equivalent thereof. Specifically, Applicant claims "[a] method of treating pain and inflammation, comprising the steps of: [1] providing a dose of Morinda citrifolia for consumption and [2] limiting undesired COX-1 inhibition relative to COX-2 inhibition by limiting the concentration of said dose." Although Moniz discloses a method for processing the

noni plant into powder for medicinal purposes, Moniz neither discloses nor suggests a particular concentration of noni to maximize desired effects. Neither is such limited dosage disclosed or suggested by Nair or Wadsworth.

Further, the combined references fail to disclose or suggest a method of "treating pain and inflammation" as claimed by the present invention. Applicant finds no mention of this element in any cited reference, nor any equivalent thereof. Since the combined prior art references fail to teach or suggest all claim limitations of the present invention, Applicant submits that the present invention is not obvious. MPEP § 2143.

In addition, there is no motivation or suggestion to combine the above references. As discussed previously, Moniz teaches a method for processing the noni plant into powder. Moniz in no way suggests utilizing noni in combination with a fruit extract to produce a food supplement as disclosed by Nair. Likewise, Nair does not suggest or motivate one skilled in the art to utilize pure noni, such as that disclosed by Moniz and Wadsworth, as an ingredient in the food supplement. Nair, in fact, teaches away from the use of pure noni. Indeed, Nair specifies that for effective maximization of the food supplement's anti-inflammatory effect, an anthocyanin-containing plant must be processed to reduce the anthocyanin to anthocyanidin. It would not be obvious to one skilled in the art to substitute a form of pure noni for an anthocyanin-containing plant that has been processed to isolate the non-naturally occurring anthocyanidin, such as that disclosed by Nair.

Applicant's claims 2-14 place further limitations on otherwise allowable subject matter and are not therefore obvious in light of the prior art.

In light of the absence of any suggestion or motivation to combine the above-referenced prior art, the mere fact that such prior art could be combined in the manner suggested by the Examiner

does not render the present invention obvious. MPEP § 2142. Moreover, in this case the combined references fail to produce or suggest each element of the claimed invention. Applicant thus respectfully requests withdrawal of the rejections of claims 1-14 under Section 103 in view of Moniz, Nair, and Wadsworth.

Conclusion

Based on the foregoing, Applicant believes that the claims of the present invention, as amended, are in condition for allowance and respectfully requests the same.

Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to initiate a telephone interview with undersigned counsel.

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Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

9. (Amended) A method of treating pain and inflammation comprising the steps of:

obtaining a quantity of Morinda citrifolia juice and pulp; filtering the wet pulp from the juice;

pasteurizing the juice; and

providing a dose of said Morinda citrifolia juice for consumption, wherein said dose is administered in an amount that is pre-determined to limit undesired COX-1 inhibition relative to COX-2 inhibition.

11. (Cancel).

12. (Amended) A method of treating pain and inflammation comprising the steps of:

obtaining a quantity of Morinda citrifolia juice and pulp; filtering the wet pulp from the juice, wherein the wet pulp has a fiber content of from 10% to 40%, by weight;

pasteurizing the pulp; and

providing a therapeutic dose of said Morinda citrifolia pulp for consumption, wherein said dose is administered in an amount that is pre-determined to limit undesired COX-1 inhibition relative to COX-2 inhibition.

14. (Cancel).